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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M2139n

CFN 1123554

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

October 6, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Ronnie D. Compton, President
Virginia Medical and Respiratory Equipment, Inc.
Route 460, P.O. Box 1380
Grundy, Virginia 24614

Dear Mr. Compton:

The Food and Drug Administration (FDA) conducted an inspection of your Grundy, Virginia facility on September 21, 1998. During the inspection, deviations from the Current Good Manufacturing Practice Regulations (CGMP), (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211), were observed. These deviations cause your Oxygen, USP to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The deviations included the following:

1. Failure to document calibration of instruments used in the manufacture and testing of Oxygen, USP in accordance with the manufacturer's instructions and/or approved procedures, to include:

   a. [redacted]oxygen analyzer
   b. [redacted]thermometer
   c. pressure and vacuum gauges

2. Failure to establish adequate written production and process control procedures covering all critical aspects of manufacturing operations. For example, no documentation was available to demonstrate that transfilling procedures were approved by responsible individuals, nor did the procedures include a post-fill odor test.

3. Failure to establish accurate and complete batch production records for each batch of Oxygen, USP, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished. For example, the oxygen purity test was not documented for a lot of transfilled E

cylinders; temperature and pressure readings for transfilling differed; an Oxygen purity reading of 99.5% was recorded in batch records regardless of the actual analyzer results; and a second odor test during post-fill testing was not documented.

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Federal agencies are advised of the issuance of all Warning Letters concerning drugs and devices so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction. Enclosed is a compressed medical gases guideline which discusses the applicability of the CGMP Regulations to medical gas manufacturers.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Northern Virginia Resident Post, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller can be reached at (703) 235-8440, extension 504.

Sincerely,

Bradford W. Williams
Acting Director, Baltimore District

Enclosure